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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/584,983	04/12/2007	Taehwan Kwak	CMT-0069	2395

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EXAMINER	
HOFFMAN, SUSAN COE	
ART UNIT	PAPER NUMBER
1655	

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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/584,983	KWAK ET AL.	
	Examiner	Art Unit	
	Susan Coe Hoffman	1655	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *24 April 2008*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1 and 6-41* is/are pending in the application.

4a) Of the above claim(s) *11,13,15,18-20,22-27,30 and 32-34* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1,6-10,12,14,16,17,21,28,29,31 and 35-41* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *4/07; 11/06*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

1. The amendments filed September 12, 2007, December 18, 2007 and April 24, 2008 have been received and entered.

2. Claims 2-5 have been cancelled.

3. Claims 1 and 6-41 are currently pending.

Election/Restrictions

4. Applicant's election with traverse of cryptotanshinone and tanshinone IIA for species A, 1-beta-hydroxycryptotanshinone for species B and obesity for species C in the replies filed on April 24, 2008 and December 18, 2008 is acknowledged. The traversal is on the ground(s) that the composition claimed in claim 1 is distinguishable over the prior art due to the presence of synergism as shown in the specification. This is not found persuasive because applicant's claim for unexpected results based on synergism is not sufficient to overcome the anticipatory references discussed below. The elected composition is not considered allowable. Furthermore, the anticipatory references discussed below also demonstrate the lack of unity between the different compositions claimed in claim 1 because the references anticipate the elected species and do not necessarily anticipate the other compositions encompassed by the claims.

The requirement is still deemed proper and is therefore made FINAL.

5. Claims 11, 13, 15, 18-20, 22-27, 30, 32-34 are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected species, there being no allowable generic or linking claim. Applicant timely traversed the restriction (election) requirement in the

replies filed on April 24, 2008 and December 18, 2008. Please note that claims 20 and 22-27 are withdrawn because these claims require the presence of a non-elected ingredient.

6. Claims 1, 6-10, 12, 14, 16, 17, 21, 28, 29, 31 and 35-41 are examined on the merits. Claims 1, 6-10, 12, 14, 16, 17, 21, 28, 29, 31 and 35-39 are examined on the merits solely in regards to the elected species.

Claim Objections

7. Claims 16, 17 are objected to under 37 CFR 1.75(c), as being of improper dependent form for failing to further limit the subject matter of a previous claim. Applicant is required to cancel the claim(s), or amend the claim(s) to place the claim(s) in proper dependent form, or rewrite the claim(s) in independent form. Claims 16 and 17 depend on claim 1 which requires at least two components selected from cryptotanshinone, tanshinone IIA, tanshinone I and 15,16-dihydrotanshinone I. However, claim 16 and 17 only require one of these ingredients because the second ingredient being claimed as "optional." The requirement for only one ingredient conflicts with claim 1 and improperly broadens the scope of the claims.

8. Claim 10 is objected to because of the following informalities: "therebetween" should properly be "there between". Appropriate correction is required.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

9. Claims 1, 6-10, 12, 14, 16, 17, 21, 28, 29, 31 and 35-39 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for reducing obesity, does not reasonably provide enablement for preventing obesity. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to practice the invention commensurate in scope with these claims.

Undue experimentation would be required to practice the invention as claimed due to the quantity of experimentation necessary; limited amount of guidance and limited number of working examples in the specification; nature of the invention; state of the prior art; relative skill level of those in the art; predictability or unpredictability in the art; and breadth of the claims. In re Wands, 8 USPQ2d 1400, 1404 (Fed. Cir. 1988).

Applicant's claims are broadly drawn to a composition that is able to prevent obesity. In order to be enabled for prevention of a condition, applicant must demonstrate that the invention is able to prevent the condition in each and every instance of that condition. Applicant's specification does not set forth any evidence that the claimed product is able to prevent obesity for all potential causes of obesity. In addition, the art teaches that obesity can only be prevented using lifestyle modification to inhibit weight gain (see http://mayoclinic.com/health/obesity/DS00314/DSECTION=prevention). Furthermore, it is well known that there is no specific drug treatment that can absolutely prevent weight gain. Thus, since applicant's specification does not show prevention of obesity and the art acknowledges that prevention is not currently possible, a person of ordinary skill in the art would be forced to experiment unduly in order to determine if applicant's invention actually function as claimed. Therefore, the claims are not considered enabled for the prevention of obesity.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 16, 17, 40 and 41 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

10. As discussed above in paragraph 7, claims 16 and 17 conflict with the scope of claim 1. Thus, the metes and bounds of claims 16 and 17 are indefinite because it is unclear exactly what ingredients are required in the claim.

11. Claim 40 is rendered indefinite by the use of parentheses around "vacuum." It is unclear if this limitation is a required part of the claim.

12. Claim 41 is indefinite because it is unclear what characteristics the Danshen must have in order to be considered "drug material" and "raw drug material."

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

13. Claims 1, 7-10, 16, 17, 21, 28, 29, 31, 35, 37, 39 are rejected under 35 U.S.C. 102(b) as being anticipated by Sucher (US 2002/0077352).

This reference teaches a composition comprising tanshinones from Saliva miltiorrhiza (see abstract). The composition contains 7.35% cryptotanshinone and 6.72% tanshinone IIA (see

paragraph 19). These percentages result in a composition that contains the ratios claimed by applicant and in a composition with cryptotanshinone as the most abundant ingredient. The composition is formulated with carriers into oral and injectable preparations such as tablets, capsules, solutions, emulsions, and powders (see page 5).

The reference does not specifically teach that the composition has the same effects on the body as those claimed by applicant; however, since the composition taught by the reference is the same as the claimed composition, the reference composition would inherently have to have the same effects if applicant's invention functions as claimed.

Applicant's specification states that the combination of cryptotanshinone and tanshinone IIA is synergistic. Applicant's arguments of April 24, 2008 state that this combination is allowable based on this synergism. However, any evidence of synergy is not persuasive to overcome this rejection because the reference teaches a composition that is the same as the claimed composition. As discussed in MPEP section 716.02 " Any *differences* between the claimed invention and the prior art may be expected to result in some differences in properties. The issue is whether the properties differ to such an extent that the difference is really unexpected" (emphasis added). Since the prior art composition anticipates the claimed composition there are no differences between the two. Thus, evidence of unexpected results are not considered persuasive to overcome this rejection.

14. Claims 1, 7, 14, 16, 17, 21, 28, 29, 31 are rejected under 35 U.S.C. 102(b) as being anticipated by Tezuka (Chem. Pharm. Bull. (1997), vol. 45, no. 8, pp. 1306-1311).

This reference teaches a S. miltiorrhiza extract that contains 0.010% cryptotanshinone and 0.13% tanshinone (see Chart 2).

The reference does not specifically teach that the composition has the same effects on the body as those claimed by applicant; however, since the composition taught by the reference is the same as the claimed composition, the reference composition would inherently have to have the same effects if applicant's invention functions as claimed.

Applicant's specification states that the combination of cryptotanshinone and tanshinone IIA is synergistic. Applicant's arguments of April 24, 2008 state that this combination is allowable based on this synergism. However, any evidence of synergy is not persuasive to overcome this rejection because the reference teaches a composition that is the same as the claimed composition. As discussed in MPEP section 716.02 " Any *differences* between the claimed invention and the prior art may be expected to result in some differences in properties. The issue is whether the properties differ to such an extent that the difference is really unexpected (emphasis added)." Since the prior art composition anticipates the claimed composition there are no differences between the two. Thus, evidence of unexpected results are not considered persuasive to overcome this rejection.

15. Claims 1, 16, 17, 21, 28, 29, 31, 35, 37 and 39-41 are rejected under 35 U.S.C. 102(b) as being anticipated by Wei (US 6,541,046).

This reference teaches a composition for controlling body weight comprising an extract from S. miltiorrhiza which contains tanshinone IIA and cryptotanshinone (see column 9, lines 1-4). The extract is prepared by extracting the plant in water, filtering the extract and then condensing (concentrating) the extract (see column 10). The composition is formulated into powders, capsules, or tablets or is added to foods or beverages (see column 1, lines 22-65).

Applicant's specification states that the combination of cryptotanshinone and tanshinone IIA is synergistic. Applicant's arguments of April 24, 2008 state that this combination is allowable based on this synergism. However, any evidence of synergy is not persuasive to overcome this rejection because the reference teaches a composition that is the same as the claimed composition. As discussed in MPEP section 716.02 " Any *differences* between the claimed invention and the prior art may be expected to result in some differences in properties. The issue is whether the properties differ to such an extent that the difference is really unexpected (emphasis added)." Since the prior art composition anticipates the claimed composition there are no differences between the two. Thus, evidence of unexpected results are not considered persuasive to overcome this rejection.

16. Claims 1, 16, 17, 21, 28, 29, 31, 35-41 are rejected under 35 U.S.C. 102(b) as being anticipated by Tashiro (US 5,589,182).

This reference teaches an extract from S. miltiorrhiza which contains tanshinone B and tanshinone C (see column 10, lines 14-18). Tanshinone B is another name for tanshinone IIA (see Registry entry for tanshinone IIA), and tanshinone C is another name for cryptotanshinone (see Registry entry for cryptotanshinone). The extract is made by extracting the plant material with water, filtering the extract and concentrating the extract (see column 7, lines 50-60 and column 8, lines 7-10). The composition is formulated into oral pharmaceuticals such as powders, tablets, capsules, or drinks. The composition is also formulated as an injectable solution. The pharmaceuticals contain 2 to 50% of the active ingredients and are administered at a dosage of 20 to 600 mg/kg/day (see column 8, lines 7-42).

The reference does not specifically teach that the composition has the same effects on the body as those claimed by applicant; however, since the composition taught by the reference is the same as the claimed composition, the reference composition would inherently have to have the same effects if applicant's invention functions as claimed.

Applicant's specification states that the combination of cryptotanshinone and tanshinone IIA is synergistic. Applicant's arguments of April 24, 2008 state that this combination is allowable based on this synergism. However, any evidence of synergy is not persuasive to overcome this rejection because the reference teaches a composition that is the same as the claimed composition. As discussed in MPEP section 716.02 " Any *differences* between the claimed invention and the prior art may be expected to result in some differences in properties. The issue is whether the properties differ to such an extent that the difference is really unexpected (emphasis added)." Since the prior art composition anticipates the claimed composition there are no differences between the two. Thus, evidence of unexpected results are not considered persuasive to overcome this rejection.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

17. Claims 1, 7-10, 14 and 35-39 are rejected under 35 U.S.C. 103(a) as being unpatentable over Sucher (US 2002/0077352).

The teachings of this reference are discussed above. The reference does not specifically using the cryptotanshinone and tanshinone IIA in the ratios claimed by applicant or using these ingredients in the percentages and dosages claimed in claims 36 and 38. However, the amount of a specific ingredient in a composition is clearly a result effective parameter that a person of ordinary skill in the art would routinely optimize. "[W]here the general conditions of a claim are disclosed in the prior art, it is not inventive to discover the optimum or workable ranges by routine experimentation." In re Aller, 220 F.2d 454, 456, 105 USPQ 233, 235 (CCPA 1955). The reference specifically teaches that the dosage of each ingredient can be chosen by the individual physician in view of the patient's condition, age, body weight and response to the drug. In addition, the reference teaches adjusting the dosages to produce appropriate plasma levels of the ingredients (see paragraphs 50 and 59). Thus, the reference acknowledges that the amount of each ingredient can be varied to best suit the individual undergoing treatment. Therefore, it would have been customary for an artisan of ordinary skill to determine the optimal amount of each ingredient to add in order to best achieve the desired results. Thus, absent some demonstration of unexpected results from the claimed parameters, this optimization of ingredient amount would have been obvious at the time of applicant's invention.

Applicant's specification does state that the combination of cryptotanshinone and tanshinone IIA is synergistic. However, the results shown the in specification are not considered to show that the specific amount of the ingredient itself produces unexpected synergistic results rather than expected additive results. Furthermore, even if unexpected results were seen, they would not be commensurate in scope with all of the ratios encompassed by the claims (see MPEP section 716.02 (d)).

The reference also does not specifically teach using all of the dosage forms claimed by applicant. However, these are well known dosage forms that would be obvious for an artisan of ordinary skill to employ.

18. Claims 1, 6, 16, 17, 21, 28, 29, 31, 35 and 39 are rejected under 35 U.S.C. 103(a) as being unpatentable over Sairafianpour (J. Nat. Prod. (2001), vol. 63, pp, 1398-1403) and Yuan (CN 1264580).

Sairafianpour teaches the pharmaceutical effects of both cryptotanshinone and 1-beta-hydroxycryptotanshinone. The reference teaches that both of these compounds function against human carcinoma (see abstract). The reference also teaches that cryptotanshinone is from S. miltiorrhiza (see page 1398).

Yuan teaches using tanshinone IIA to treat human carcinomas (see English abstract).

These references show that it was well known in the art at the time of the invention to use the claimed ingredients in compositions that treat carcinoma. It is well known that it is prima facie obvious to combine two or more ingredients each of which is taught by the prior art to be useful for the same purpose in order to form a third composition which is useful for the same purpose. The idea for combining them flows logically from their having been used individually in the prior art. In re Pinten, 459 F.2d 1053, 173 USPQ 801 (CCPA 1972); In re Susi, 58 CCPA 1074, 1079-80; 440 F.2d 442, 445; 169 USPQ 423, 426 (1971); In re Crockett, 47 CCPA 1018, 1020-21; 279 F.2d 274, 276-277; 126 USPQ 186, 188 (1960).

Based on the disclosure by these references that these substances are used in compositions to treat carcinoma, an artisan of ordinary skill would have a reasonable expectation that a combination of the substances would also be useful in creating compositions to treat

carcinoma. Therefore, the artisan would have been motivated to combine the claimed ingredients into a single composition. No patentable invention resides in combining old ingredients of known properties where the results obtained thereby are no more than the additive effect of the ingredients. See In re Sussman, 1943 C.D. 518; In re Huellmantel 139 USPQ 496; In re Crockett 126 USPQ 186.

The references also do not specifically teach formulating the ingredients into the pharmaceutical forms claimed. However, these are well known pharmaceutical forms that would have been obvious for one of ordinary skill in the art to employ. Thus, the use of these forms is considered to be an obvious modification of the references.

The references not specifically teach that the composition has the same effects on the body as those claimed by applicant; however, since the composition taught by the reference is the same as the claimed composition, the reference composition would intrinsically have to have the same effects if applicant's invention functions as claimed.

19. No claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Susan Coe Hoffman whose telephone number is (571) 272-0963. The examiner can normally be reached on Monday-Thursday, 9:30-5:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Terry McKelvey can be reached on (571) 272-0775. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Susan Coe Hoffman/
Primary Examiner, Art Unit 1655